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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/606,202 | 06/24/2003 | Andrew D. Firlík | 33734-8046US | 4373 |

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SEATTLE, WA 98111-1247

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| EXAMINER |
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ALTER, ALYSSA M

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| ART UNIT | PAPER NUMBER |
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3762

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/17/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/606,202 | Applicant(s) FIRLIK ET AL. | |
| | Examiner Alyssa M. Alter | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/22/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 30-44 have been considered but are moot in view of the new ground(s) of rejection in view of Normann et al. (US 5,215,088 A), Dobelle (US 6,658,299 B1) and John (US 6,066,163) in response to the amendment to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 include an improper Markush group.

A Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). Ex parte Markush sanctions claiming a genus expressed as a group consisting of certain specified materials.

The examiner recommends changing "behavior therapy **comprises** having the patient engage in at least one of" to "behavior therapy includes at least one selected from the group **consisting of**--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 30, 32-35, 39 and 41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Normann et al. (US 5,215,088 A). Normann et al. discloses a three-dimensional electrode device for providing cortical stimulation.

As to claim 30, the electrode array device functions as a visual prosthesis by converting a visual image captured by a video camera into electric signals and then providing these signals to the electrode array. The array then provides cortical stimulation and produces phosphenes in response to the image. As a result the "the blind person perceives the image in his mind, thus providing a usable sense of sight"(col. 4, lines 31-32). As a result, the sensed and synthesized images are preformed simultaneously with the cortical stimulation.

As to claims 30, 35, 39 and 41-44, the examiner considers the sensed and synthesized images, artificial sight, to be a behavior therapy. This behavior therapy, of artificial sight, is having the patient engage in a visual task, an activity of daily living, a reading task and an attention task. Additionally, the examiner considers artificial sight to be having the patient engage in a comprehension task, since the patient tries to decipher the images synthesized.

As to claim 32, the synthesis of artificial vision is utilized for a specific length of time so that a "blind person" can recover their functional ability to see.

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2. Claims 30, 32-35, 39 and 41-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Dobelle (US 6,658,299 B1). Dobelle discloses an artificial vision system that camera which senses an image and then provides electrical stimulation to create phosphenes. As a result, the sensed and synthesized images are preformed simultaneously with the cortical stimulation.

As to claims 30, 35, 39 and 41-44, the examiner considers the sensed and synthesized images, artificial sight, to be a behavior therapy. This behavior therapy, of artificial sight, is having the patient engage in a visual task, an activity of daily living, a reading task and an attention task. Additionally, the examiner considers artificial sight to be having the patient engage in a comprehension task, since the patient tries to decipher the images synthesized.

As to claim 32, the synthesis of artificial vision is utilized for a specific length of time so that a "blind person" can recover their functional ability to see.

3. Claims 30-41 and 38-42, 44 are rejected under 35 U.S.C. 102(e) as being anticipated by John (US 6,066,163). John disclosed an adaptive brain stimulation that aids in rehabilitation of patients suffering from traumatic brain injury, coma and other brain dysfunction.

As to claim 30, John discloses in col. 14, lines 43-50, "Sensory stimulation achieves excitation of such areas as the reticular formation, lemniscal pathways, specific and non-specific and cortical regions. Using the ABS, sensory stimulation parameters including intensity, duration, and frequency can be modified and the

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corresponding resultant present state compared to a reference state in order to choose the optimum stimulation parameters for creating cortical excitation”.

As to claims 30 and 35, 37, 39-42, “the ABS system and method also contains devices for auditory stimulation such as headphones 56a, for visual stimulation such as LED goggles 56b, and for somatosensory stimulation such as a tactile stimulator 56c that is attached to the wrist or fingers of the subject, all of which are controlled and powered by the PC. These stimulation device enable the generation of auditory, visual, and somatosensory transient evoked potentials and steady state potentials that can be recorded from the EEG electrodes”(col. 5, lines 15-23).

The therapy that includes the use of LED goggles for visual stimulation elicits a visual stimulus, and thus is a visual task. Visual stimulus is also a reading task and attention task. Also, tactile stimulation would naturally be “volitional use of an affected body part” as claimed by the Applicant, as well as part of the “activities of daily living” and physical therapy. In addition, the behavior therapy occurs simultaneously with electrical or cortical stimulation therapy.

As to claim 38, “in addition to the previously described types of direct electrical brain stimulation, stimulation of all five senses, both separately and in combination, has been shown to be effective in decreasing the time spent in coma (Sosnowski C, et al. Early intervention: coma stimulation in the intensive care unit. J Neurosci Nurs. 1994 December; 26(6): 336-341; Mitchell S, et al. Coma arousal procedure: a therapeutic intervention in the treatment of head injury. Brain Inj. 1990 July; 4(3): 273-279. Wood

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R L, et al. Evaluating sensory regulation as a method to improve awareness in patients with altered states of consciousness: a pilot study. Brain Inj. 1992 September; 6(5): 411-418.)" (col. 14, lines 32-43). Therefore, sensory stimulation affects awareness and thus provides cognitive therapy.

30 and 36, "a present state of a patient can be divided into a "stimulation period" and a "post-stimulus period." The stimulation period is defined as a period that is in, or is temporally close to, the period in which stimulation occurs, for example from stimulation onset until stimulation offset or lasting up to, for example, 1 second post-stimulus 62c. The stimulation period may also be sub-divided into two or more smaller sections of interest 62a, 62b. The "post-stimulus period" may similarly be a single period or may be divided into two or more sub-periods 62c, 62d, 62e which begin after the stimulation period and last until the next stimulation period. The post-stimulus period may be characterized by complete cessation of stimulation or by a relatively decreased level of stimulation compared to the stimulator state." (col. 6, lines 54-67). John describes the post-stimulus lasting until the next stimulation period, which is indicative "of a therapy period that includes at least one session", as claimed by Applicant.

As to claims 31-32, "After the patient regains consciousness by returning from the coma or manifest an other desired improvement by recovering from a dysfunctional state, the ABS system can be implanted into a patient and aid in the subsequent maintenance of the normal state"(col. 3, lines 63-67). Thus, stimulation is ceased when a "predetermined level of functional recovery" is achieved, as claimed by Applicant.

As to claims 33-34, the direct brain stimulator (DBS) 50 is depicted in figure 1.
"DBS's can consist of implanted electrodes or stimulating devices"(col. 12, lines 55-56).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 45-46 are rejected under 35 U.S.C. 102(e) as anticipated by John (US 6,066,163) or, in the alternative, under 35 U.S.C. 103(a) as obvious over John (US 6,066,163) in view of Collins (US 5,782,873).

As to claims 45-46, John discloses "both electrical and pharmacological stimulation can be used together to further improve the patients condition. In one application, infusion of a substance intrinsically excitatory to a particular region is made contingent upon a specific pattern of cellular firing or upon an increase of a specific frequency in the EEG. Local administration of a neurotransmitter contingent upon a particular firing pattern increases the chances for subsequent repetition of this pattern. Thus, linking the infusion of a region-appropriate substance such as norepinephrine into the reticular region to a state of increased excitability should facilitate the probability of an increase in increase in subsequent firing rates"(col. 13, lines 14-25). The infusion of a intrinsically excitatory substance will provide low threshold stimulation that cause a region to be in an increased excitability and enables an increase in subsequent firing.

In the alternative, John discloses the device substantially as claimed but fails to teach delivery of stimulation below a threshold level for neurons at the stimulation site. Collins teaches that it is known to input sub-threshold stimulus to the sensory cell area for the purpose of effectively lowering the threshold of the sensory cells. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the stimulation signal as taught by John with the sub-threshold stimulation signal as taught by Collins, in order to effectively lower the threshold of the sensory cells to facilitate enhancement in healthy individuals and treatment for those whose sensory system is degraded by disease, such as peripheral neuropathies or strokes.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 35 and 40 recite the limitation "volitional" in line 4 and line 2, respectful. The specification does not provide antecedent basis for the limitation "volitional use".

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

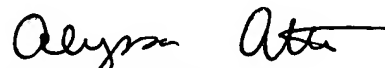
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Alyssa M Alter
Examiner
Art Unit 3762


GEORGE R. EVANISKO
PRIMARY EXAMINER

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